

10/26/2007

Dkt. #639-B-PCT-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nai-Kong CHEUNG  
U.S. Serial No. : 10/621,027  
Confirmation No. : 2089  
Filed : July 16, 2003  
Examiner : 1623  
Art Unit : Eric Olson  
For : THERAPY-ENHANCING GLUCAN

Law Offices of Albert Wai-Kit Chan, PLLC  
World Plaza, Suite 604  
141-07 20<sup>th</sup> Avenue  
Whitestone, NY 11357

October 26, 2007

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with his duty of disclosure under 37 C.F.R. §1.56, Applicant would like to direct the Examiner's attention to the following references which are listed on Forms PTO/SB/08A and PTO/SB/08B (attached hereto as **Exhibit A**), and the individual references further attached as **Exhibits 1-20**.

Reference 1 is a U.S. Patent, and reference 2 is a U.S. Patent Publication. Both are on file at the USPTO; therefore copies will not be provided. Applicant's attorney's office may be contacted in the event that the Examiner would like a copy of the reference.

/ESO/ 1. U.S. Patent No. 7,070,778, July 4, 2006, YVIN et al.,  
"Therapeutic Combination Against Cancer."

/Eric Olson/

12/10/2007

Applicant : Nai-Kong CHEUNG Atty. Dkt. No. : 639-B-PCT-US  
USSN : 10/621,027 Art Unit : 1623  
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IESO/ 2. U.S. Patent Publication No. US 2003/0180254 A1,  
September 25, 2003, LANE et al., "Immunologic  
enhancement with intermittent interleukin-2 therapy."

/ESO/ 3. PCT Written Opinion for SLOAN-KETTERING INSTITUTE FOR  
CANCER RESEARCH et al., Int'l appl No. PCT/US02/01276,  
(Atty. Dkt. #639-A-PCT), Filed January 15, 2002, Dated  
November 25, 2002. [Exhibit 1]

4. PCT Corrected Written Opinion of the International  
/ESO/ Searching Authority for SLOAN Kettering Institute et  
al., Int'l Application No. PCT/US04/23099 (Atty. Dkt.  
#639-C-PCT), Filed July 16, 2004, Dated August 10,  
2005. [Exhibit 2]

5. PCT Corrected International Search Report for SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH et al., Int'l Application No. PCT/US2004/23099 (Atty. Dkt. #639-C-PCT), Filed July 16, 2004, Dated August 10, 2005.  
[Exhibit 3]

/ESO/ 6. PCT International Preliminary Report on Patentability for SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH et al., Int'l Appl No. PCT/US2004/023099 (Atty. Dkt. #639-C-PCT), Filed July 16, 2004, Dated January 26, 2006.  
[Exhibit 4]

7. PCT International Search Report for SLOAN-KETTERING  
/ESO/ INSTITUTE FOR CANCER RESEARCH, Int'l. Application No.  
PCT/US07/01427 (Atty. Dkt. #639-F-PCT), Filed January  
18, 2007, Dated September 26, 2007. [Exhibit 5]

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/Eric Olson/

Applicant : Nai-Kong CHEUNG Atty. Dkt. No. : 639-B-PCT-US  
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8. PCT Written Opinion of the International Searching Authority for SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Int'l Application No. PCT/US07/01427 (Atty. Dkt. #639-F-PCT), Filed January 18, 2007, Dated September 26, 2007. [Exhibit 6]

9. Beta Glucan Health Center webpage, November 10, 2000,  
/ESO/ "PLEURAN- Beta-1,3/1-6-Glucan,"  
<http://www.glucon.com/therapy/therapy.com>. [Exhibit 7]

10. BOHN, J.A., and BeMiller, J.N., 1995, "(1-3)- $\beta$ -Glucans as biological response modifiers: a review of structure-functional activity relationships," Carbohydrate Polymers, 28:3-14. [Exhibit 8]

11. CHEUNG, N.-K. V., et al., June 1985, "Monoclonal  
Antibodies to a Glycolipid Antigen on Human  
Neuroblastoma Cells," Canc. Res., 45:2642-2649.  
[Exhibit 9]

12. HELLSTROM, I. et al., September 1986, "Antitumor  
/ESO/ effects of L6, and IgG2a antibody that reacts with most  
human carcinomas," Proc. Natl. Acad. Sci. USA, 83:7059-  
7063. [Exhibit 10]

13. KIM, Y.-S., et al., October 20, 2000, "Gram-negative  
Bacteria-binding Protein, a Pattern Recognition  
Receptor for Lipopolysaccharide and  $\beta$ -1,3-Glucan That  
Mediates the Signaling for the Induction of Innate  
Immune Genes in *Drosophila melanogaster* Cells," J.  
Biol. Chem., 275(42):32721-32727. [Exhibit 11]

14. KOTERA, Y., et al., June 1, 1994, "Humoral Immunity against a Tandem Repeat Epitope of Human Mucin MUC-1 in

Applicant : Nai-Kong CHEUNG Atty. Dkt. No. : 639-B-PCT-US  
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Sera from Breast, Pancreatic, and Colon Cancer Patients," Cancer Res., 54:2856-2860. [Exhibit 12]

/ESO/ 15. MATZINGER, P., 1994, "Tolerance, Danger, and the Extended Family," Annu. Rev. Immunol., 12:991-1045. [Exhibit 13]

/ESO/ 16. MENDELSOHN, J., December 1997, "Epidermal Growth Factor Receptor Inhibition by a Monoclonal Antibody as Anticancer Therapy," Clin. Cancer Res., 3:2703-2707. [Exhibit 14]

/ESO/ 17. RAI, K.R. and GUPTA, N., June 2000, "Monoclonal Antibodies in Chronic Lymphocytic Leukemia," Rev. Clin. Exp. Hematol., 4.2:134-144. [Exhibit 15]

/ESO/ 18. SLOVIN, S.F. et al., May 1999, "Carbohydrate vaccines in cancer: Immunogenicity of a fully synthetic globo H hexasaccharide conjugate in man," Proc. Natl. Acad. Sci. USA, 96:5710-5715. [Exhibit 16]

/ESO/ 19. ZIMMERMAN, J.W., et al., August 21, 1998, "A Novel Carbohydrate-Glycosphingolipid Interaction between a  $\beta$ -(1-3)-Glucan Immunomodulator, PGG-glucan, and Lactosyceramide of Human Leukocytes," J. Biol. Chem., 273(34):22014-22020. [Exhibit 17]

/ESO/ 20. U.S. Office Action for Nai-Kong V. CHEUNG, U.S. Serial No. 11/218,044, Filed August 31, 2005, Dated March 10, 2006 (Atty. Dkt. #639-BZ-PCT-US). [Exhibit 18]

/ESO/ 21. U.S. Office Action for Nai-Kong V. CHEUNG, U.S. Serial No. 11/218,044, Filed August 31, 2005, Dated

Applicant : Nai-Kong CHEUNG Atty. Dkt. No. : 639-B-PCT-US  
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November 22, 2006 (Atty. Dkt. #639-BZ-PCT-US). [Exhibit 19]

22. U.S. Office Action for Nai-Kong v. CHEUNG, U.S.  
/ESO/ Serial No. 11/218,044, Filed August 31, 2005, Dated  
August 7, 2007 (Atty Dkt. #639-BZ-PCT-US). [Exhibit 20]

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below. No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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/Eric Olson/

12/10/2007

12/17/2007

PTO/SB/08A (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

Approved for use through September 30, 2007  
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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 1 of 6

**Complete if Known**

Application Number	10/621,027
Filing Date	July 16, 2003
First Named Inventor	CHEUNG, Nai-Kong V.
Art Unit	1623
Examiner Name	Eric Olson
Attorney Docket Number	639-B-PCT-US

**U. S. PATENT DOCUMENTS**

## FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> ~Number <sup>4</sup> ~Kind Code <sup>5</sup> (if known)				
/ESO/	16	WO 2007084661	07-26-2007	Sloan-Kettering Institute for Cancer Research		
/ESO/	17	WO 2006085895	08-17-2006	Biopolymer Engineering Inc et al.		
/ESO/	18	WO 2005049044	06-02-2005	Laboratoires Goemar SA		
/ESO/	19	WO 2004030613	04-15-2004	University of Louisville Research Foundation, Inc.		
/ESO/	20	WO 02058711	08-01-2002	Sloan-Kettering Institute for Cancer Research		
/ESO/	21	WO 2006119395	11-09-2006	Biopolymer Engineering		

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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
/ESO/	22	WO 0180807	11-01-2001	Goemar Lab SA		
/ESO/	23	WO 2005027938	03-31-2005	Goemar Lab SA		
/ESO/	24	WO 03004507	01-16-2003	Research Center for Eco-Environmental Sciences		
/ESO/	25	WO 0168105	09-20-2001	Societas Cooperativa Centro Andina Politecnica Responsabilida' Limitada'		
/ESO/	26	WO 2005027936	03-31-2005	Laboratoires Goemar SA		
/ESO/	27	EP0194851	09-17-1986	The Wistar Institute		

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/ESO/	4	U.S. Publication No. US-2006-0020128, January 26, 2006, Nai-Kong CHEUNG, "Therapy-Enhancing Glucan."	
/ESO/	5	U.S. Publication No. US-2006-0188506, August 24, 2006, Nai-Kong CHEUNG, "Therapy-Enhancing Glucan."	
/ESO/	6	U.S. Publication No. US-2007-0059310, March 15, 2007, Steven KAREL, "Therapeutic combination compositions and methods of using same."	
/ESO/	7	U.S. Publication No. US-2006-0165700, July 27, 2006, OSTROFF et al., "Cancer therapy using whole glucan particles and antibodies."	
/ESO/	8	U.S. Publication No. US-2005-0118187, June 2, 2005, Baofa YU, "Combinations and methods for treating neoplasms."	
/ESO/	9	U.S. Publication No. US-2007-0134259, June 14, 2007, BUNDLE et al., "Methods and compositions for pharmacologically controlled targeted immunotherapy."	
/ESO/	10	U.S. Publication No. US-2007-0020232, January 25, 2007, ROSSIGNOL et al., "Compositions and methods for cancer immunotherapy."	
/ESO/	11	U.S. Publication No. US-2006-0009419, January 12, 2006, Gordon D. ROSS, "Cancer Therapy using beta glucan and antibodies."	
/ESO/	12	U.S. Publication No. US-2005-0208079, September 22, 2005, CASSONE et al., "Glucan-based vaccines."	
/ESO/	13	U.S. Publication No. US-2002-0044919, April 18, 2002, Baofa YU, "Combinations and methods for treating neoplasms."	

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/ESO/	14	U.S. Publication No. US-2006-0263355, November 23, 2006, QUAN et al., "Treatment of bone disorders."		
/ESO/	15	U.S. Publication No. US-2002-0119928, August 29, 2002, MCANALLEY et al., "Dietary supplement compositions."		
/ESO/	28	ADACHI et al., 1990, "Macrophage Activation in Vitro by Chemically Cross-Linked (1-3)- $\beta$ -D-Glucans", Chem. Pharm. Bull., 38(4):988-992.		
/ESO/	29	AZUMA, Ichiro, "Development of Immunostimulants in Japan", Immunostimulants: Now and Tomorrow, 41-56.		
/ESO/	30	BLUHM et al., 1977, "The triple helical structure of lentinan, a linear $\beta$ -(1 $\rightarrow$ 3)-D-glucan", Can J Chem, 55:293-299.		
/ESO/	31	BOGWALD et al., 1982, "The Cytotoxic Effect of Mouse Macrophages Stimulated in Vitro by a $\beta$ -1,3-D-Glucan from Yeast Cell Walls", Scandinavian Journal of Immunology, 15:297-304.		
/ESO/	32	CHIHARA et al., 1982, "Current Status and Perspectives of Immunomodulators of Microbial Origin", International Journal of Tissue Reactions, 4:207-225.		
/ESO/	33	MAEDA et al., 1971, "Lentinan, a new immune-accelerator of cell-mediated responses", Nature, 229:634.		
/ESO/	34	CHIHARA et al., 1970, "Fractionation and purification of the polysaccharides with Marked Antitumor Activity, Especially Lentinan, from Lentinus edodes (Berk.) Sing. (an Edible Mushroom)", Cancer Res, 30:2776-2781.		
/ESO/	35	CHIHARA et al., 1981, "The antitumor polysaccharide Lentinan: an overview", Manipulation of Host Defence Mechanisms, 1-16.		

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/ESO/	36	CHIHARA et al., 1987 "Antitumor and Metastasis-Inhibitory Activities of Lentinan as an Immunomodulator: An Overview", Cancer Detect. Prev. Suppl, 1:423-443.(		
/ESO/	37	DI LUZIO et al., 1985, "Glucans as Immunomodulators", Advances in Immunopharmacology, Permagon Press, NY, 369-375		
/ESO/	38	DI LUZIO et al., 1980, "Comparative Evaluation of the Tumor Inhibitory and Antibacterial Activity of Solubilized and Particulate Glucan", Recent Results in Cancer Research, 75:165-172.		
/ESO/	39	DI LUZIO, Nicholas R., 1985, "Update on the Immunomodulating Activities of Glucans", Springer Seminars in Immunopathology, 8:387-400.		
/ESO/	40	HAMURO et al., 1971, "The significance of the higher structure of the polysaccharides lentinan and pachymaran with regard to their antitumour activity", Chem. Biol. Interactions, 3:69-71.		
/ESO/	41	HAMURO et al., 1978, "Solid phase activation of alternative pathway of complement by $\beta$ -1,3-glucans and its possible role for tumour regressing activity", Immunology, 34:695-705.		
/ESO/	42	JAMAS et al., 1990, "Spectral Analysis of Glucan Produced by Wild-Type and Mutant <i>Saccharomyces cerevisiae</i> ", Carbohydrate Polymers, 13:207-219.		
/ESO/	43	PATCHEN et al., 1984, "Soluble Polyglycans Enhance Recovery from Cobalt-60-Induced Hemopoietic Injury", Journal of Biological Response Modifiers, 3:627-633.		
/ESO/	44	SAITO et al., 1977, "A C-N.M.R.-spectral study of a gel forming, branched (1 $\rightarrow$ 3)- $\beta$ -D-Glucan, (Lentinan) from <i>Lentinus edodes</i> , and its acid-degraded fractions. Structure, and Dependence of Confirmation on the Molecular Weight", Carbohydrate Research, 58:293-305.		
/ESO/	45	SASAKI et al., 1976, "Antitumor Activity of Degraded Products of Lentinan: it's Correlation with Molecular Weight", Gann, 67:191-195.		

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Sheet	6	of	6	Attorney Docket Number	639-B-PCT-US

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/ESO/	49	KIRBY et al., 1981, "Oat-bran intake selectively lowers serum low-density lipoprotein cholesterol concentrations of hypercholesterolemic men", American Journal of Clinical Nutrition, 34:824-829.	
/ESO/	50	PEAT et al., 1958, "Polysaccharides of Baker's Yeast. Part II. Yeast Glucan", Journal Chem. Soc. Part 1, 3862-3868.	

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